K060769

[redacted]psy
Sciences

JUL 25 2006

510(K) SUMMARY (21 CFR 807.92)

HYDROMARK BIOPSY SITE MARKER

510(k) Owner: Biopsy Sciences, Inc.
3433 East Fort Lowell Road, Suite 103
Tucson AZ 85716
Tel: 520-325-9086
Fax: 520-881-4686

Contact Person: Sharon Rockwell
Tel: 714-695-9269
E-mail: srockwell@writeme.com

Date Prepared: March, 2006

Trade Name: HydroMark Biopsy Site Marker

Common Name: Biopsy site marker

Classification Name: Implantable staple per 21 CFR 878.4750, FZP

Predicate Devices: Biopsy Sciences Bio-Mark Biopsy Site Marker, K023694
Biopsy Sciences Bio-Seal Lung Biopsy Site Marker, K041331
InterV brand V-Mark Breast Biopsy Site Marker with Titanium Anchor, K053518
J&J MicroMark Biopsy Clip, K970817

Device Description: The Biopsy Sciences HydroMark Biospy Site Markers are made of resorbable FocalSeal-L Surgical Sealant, the same material used in the Biopsy Sciences Lung Biopsy Site Marker. The HydroMark is visible under mammography, ultrasound and magnetic resonance imaging. It expands in the void created during biopsy and does not migrate. The FocalSeal-L hydrogel material degrades in a manner similar to absorbable sutures, via hydrolysis. The HydroMark also contains a titanium coil that provides permanent visibility under x-ray and MRI.

The HydroMark Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with the J&J Ethicon Endo-Surgery Mammotome probe. The HydroMark is deployed

by the delivery system through the Mammotome probe and is left in the void created during the biopsy procedure.

Intended Use:

The Biopsy Sciences, Inc. HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

The indications are identical to those of the predicate device, the Biopsy Sciences Bio-Mark Biopsy Site Marker.

Technological Characteristics:

The hydrogel component expands on fluid contact to fill the void created during the biopsy, leaving the HydroMark at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal Titanium coil which provides permanent visibility under x-ray and MRI.

Non-Clinical Performance Data:

Non-clinical testing included biocompatibility of the components, validation that delivery system is compatible with the commercially available Mammotome biopsy probe, and evidence that the site marker does not migrate over time. The HydroMark is highly visible under ultrasound imaging, does not migrate, and assures permanent visibility under x-ray and MRI with minimal artifacts. The device performs as intended and has the identical intended use as predicate devices previously cleared under 510(k)s.

Conclusions:

The non-clinical and animal test results demonstrate the HydroMark accurately marks the biopsy site. The testing supports a determination of substantial equivalence to products and technologies previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 25 2006

Ms. Sharon Rockwell
Vice-President, Regulatory and Clinical Affairs
Biopsy Sciences, LLC
3433 East Fort Lowell Road
TUCSON AZ 85718

Re: K060769
Trade/Device Name: HydroMark Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: NEU
Dated: June 14, 2006
Received: June 19, 2006

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060769

Device Name: HydroMark Biopsy Site Marker

Indications for Use:

The Biopsy Sciences LLC HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060769